DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AI DE Diagnostic, Co., Ltd.
C-Tech
c/o Lin Wang,
1929 Woodberry Court
Iowa City, IA 52246

JUL 23 2007

Re: k062703
Trade/Device Name: One Step HCG Urine Pregnancy Test Formats: Strip, Cassette and Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system.
Regulatory Class: Class II
Product Code: JHI, LCX
Dated: June 07, 2007
Received: June 11, 2007

Dear Lin Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

AIDE DIAGNOSTIC CO. LTD

141 Zhuzhou Road, Qingdao High-Tech Industrial Park, Shandong, P. R. China
Tel : 86-532-88606600 Fax : 86-532-88606655E-mail : aide@inddiagnostic.com

Statement of Indications for Use
[21 CFR 801. 109]

510 (K) Number: **K062703**

Deice Trade Name: **One Step HCG Urine Pregnancy Test**
Formats: Strip, Cassette and Midstream

Indications for Use:

One Step HCG Urine Pregnancy Test is a rapid device, two sites sandwich immunoassay test device designed for the qualitative determination of human chorionic gonadotropin (hCG) concentration in human urine samples, and therefore is an aid in the early detection of pregnancy. These test devices are available in the formats of strip, cassette and midstream. The midstream format is intended for OTC use. The cassette and strip format are intended for both over-the counter (OTC) use and use in clinical laboratories.

Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety
510(k) K062703

Prescription Use X (Part 21 CFR 801 Subpart D) **OR** **Over-The-Counter Use** X (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

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Statement of Indications for Use
[21 CFR 801. 109]

JUL 2 3 2007

510 (K) Number: **K062703**

Deice Trade Name: **One Step HCG Serum/Urine Combo Pregnancy Test**
Formats: Strip and Cassette

Indications for Use:

One Step HCG Serum/Urine Combo Pregnancy Test is a rapid device, two sites sandwich immunoassay test device designed for the qualitative determination of human chorionic gonadotropin (hCG) concentration in human urine or serum samples, and therefore is an aid in the early detection of pregnancy. These test devices are available in strip format and cassette format, and are intended for in vitro diagnostic professional use in clinical laboratories only.

Joan Cooper, D.V.M
Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety
510(k) K062703

Prescription Use X (Part 21 CFR 801 Subpart D) **OR** **Over-The-Counter Use** (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)